Implant body for the selective endovascular influencing of the flow situation in a blood vessel, and method for the production of an implant body

Description

The invention concerns on the one hand an implant body for the selective endovascular influencing of the flow situation in a blood vessel according to the characteristics specified in the preamble of Claim 1, and on the other hand a method for producing an implant body according to the characteristics specified in Claim 15 and the use of a twisting together, braiding or weaving process to produce an implant body.

In the treatment of tumours, aneurysms or angiomas a range of methods are known, in which at least part of the blood supply is suppressed. In the case of tumours for example, the aim of this is to kill off cells or tissue portions in a locally limited area and so to produce a necrosis of the tumour. With aneurysms, i.e. innate or acquired dilatation of blood vessels supplying the brain, the intention is to eliminate the risk of bleeding and/or growth in size of such vessel dilatations.

The blood supply can be reduced for example by introducing a liquid substance locally into the vessel system where it reacts to form a highly viscous mass which suppresses the blood circulation.

This method, however, can often not be applied with the necessary precision because the suppression of the blood supply can only take place in a non-specific manner and consequently only over a relatively large area. This necessarily implicates the surrounding tissue, leading to undesired secondary side effects.

In attempting to achieve as targeted as possible an interruption or influencing of the blood flow, implant bodies in the form of very small particles can also be introduced by means of a catheter at a suitable point into the vessel system. These are then intended to be carried by the bloodstream to their site of action. With this method too, exact positioning cannot be achieved with the necessary precision.

A further method of the prior art is to insert an implant body via a catheter with a flexible mandrel as far as the desired position, and there release the implant body from the mandrel.

Such implant bodies can be made from a wide variety of materials, such as metals, plastics or ceramics. They can also be provided with a surface coating which acts upon the bloodstream on contact therewith. Such an action can consist in the induction of local blood coagulation in the sense of an embolism. The result is to block the vessel. Another action is that pharmacodynamic substances are transferred into the bloodstream of the peripheral vessel with a defined material transfer and locally restricted action for a defined time.

A known implant body has the form of a coil or spiral resembling a helical spring, usually made of stainless steel. For reasons of production technology, however, helical implant bodies cannot be made with an outer diameter much below 250 microns, because the ratio between the wire diameter and the mean turn diameter of a spring is subject to certain limit values below which the said ratio cannot fall.

Since the implant body is relatively weak, their positioning within small peripheral vessels with their numerous convolutions also presents some problems.

Starting from the prior art, the present invention addresses the problem of providing an implant body whose design improves the technique of its use, its properties and its positioning, and which is also easier to produce.

The solution of the objective part of those aims is provided by the features specified in the characterising portion of Claim 1.

Advantageous designs of the implant body according to the invention form the object of the dependent Claims 2 to 14.

The key point of the invention is the feature that at least two strands (elongated elements) are wound at least partially around a common central axis with a constant or alternating twist direction to form an approximately centrally symmetric configuration. This makes it possible to produce an implant body with a smaller outer diameter than was hitherto possible with the previously known implant bodies. The implant body according to the invention has a large

surface area which comes in contact with the bloodstream in a predefined manner. This makes it possible in a controlled way to influence the flow situation in a blood vessel even to the point of blocking the vessel. From the standpoint of application technique as well, in particular precise positioning in the vessel, the implant body of the invention offers considerable advantages.

The invention recognises the fact that both the process of blood coagulation and the application of implant bodies are surface processes, and are therefore affected by the conditions of material transfer. The material transfer depends on the one hand on the size and condition of the surface of the implant body, and on the other hand also on the hydrodynamic flow behaviour of the blood in the surroundings of that surface. To produce effective action kinetics, an implant body must therefore have the highest possible surface-to-volume ratio. At the same time, the blood must be able to flow over the surface of the implant body in a defined way.

Consequently, the surface area of the implant body according to the invention is made as large as possible. This is done by making the implant body with inner and/or outer hollow spaces which on the one hand enlarge the surface area, and on the other hand are so configured as to constitute flow channels. This brings the surface into contact with the bloodstream in a predefined way.

For the purposes of controlled positioning inside a blood vessel of essentially cylindrical shape, it is also advantageous that the implant body according to the invention is of elongated and essentially rotationally symmetric shape. Sharp edges, which could lead to catching on or damage to the vessel walls, are avoided.

On the other hand, however, the implant body is sufficiently flexible, especially in relation to its longitudinal axis, to be inserted in position in narrow and convoluted vessels without much mechanical effort.

In its simplest form the implant body consists of two strands twisted together. Preferably however, more than two strands are incorporated. The strands can be wound around the central longitudinal axis with a constant or varying pitch.

A particularly advantageous embodiment can be produced by using strands that have length sections with different cross-sections. The implant body is then twisted or woven in such manner that in each case the length sections with the smallest cross-sections are in contact.

It is also possible for two or more strands to be twisted into essentially cylindrical spiral bodies with a common twist axis and the same direction of twist.

If at least three strands are used, a braid-like implant body can be made. For this, two of the strands at a time are crossed over in a periodic manner with the same or a periodically alternating twist direction.

The strands are wires or filaments, usually of metal, plastic, in particular polymers, or ceramic. The strands can also be provided with a surface coating. Of course, the use of other materials or combinations of different materials are conceivable.

In turn, each strand can itself be made of several filaments or cords and can thus be the product of a twisting, weaving or braiding process.

Although in principle strands with cross-sections of the most varied configuration can be used, they preferably have a round cross-section.

The strands can be connected to one another at least at one end. This is done by joining, possibly by welding. Other options are adhesive bonding or brazing.

In another advantageous embodiment of the implant body according to the invention, the strands form at least one spiral channel between them. This ensures controlled blood circulation with a long contact time between the blood and the surface of the implant body. From the standpoint of production technique, the said channel can be formed by combining wires of a metallic material with a plastic filament during preparation. In a subsequent treatment the plastic filament is then vaporised by the effect of heat. The result is to form the channel between the metallic wires.

An embodiment which develops further the general concept of the invention is for the strands to form a cylindrical mesh. For this, the implant body is made from several strands by a weaving process.

The implant body can be formed as a hollow body with a cylindrical internal channel. The internal channel can even be filled by a core or a mandrel. Via this core or mandrel pharmacodynamically active substances can in addition be applied.

Basically, it is possible to produce an implant body with an active substance that influences the nature of the surrounding tissue or the blood. For this, the active substance can be contained in a medium itself contained for example in a core. However, the active substance can also be contained in a surface coating of the implant body or parts thereof.

Another possibility is for at least one strand of the implant body to consist of a material that contains the active substance. The active substance can for example be a pharmacodynamic substance which is transferred into the bloodstream in a defined manner with a locally limited effect. For example, if needs be the blood coagulation can be inhibited or, on the contrary, promoted. The action of the implant body can also be supported or potentiated by controlled administration of a medicament or toxin.

A therapeutic effect can also be achieved by using an implant body which emits radioactive radiation. This enables the irradiation of the vessel wall and the surrounding tissue. The radiation can be produced by treating the entire implant body radioactively. Sometimes, however, it is already enough to use a single radioactive strand. Of course, the radioactivity can also be emitted by a medium contained in the implant body.

The solution of the process-related portion of the objective is embodied in the characterising features of Claim 15. Advantageous further developments are described in Claims 16 to 18.

According to the invention, to make an implant body at least two strands of a flexible material are twisted at least partially together with a constant or varying pitch to produce an approximately centrally symmetric configuration about a common central longitudinal axis. By the process of twisting or braiding, implant bodies can be produced with a substantially

smaller outer diameter than the known implant bodies, and this, using strands of the same thickness.

Besides twisting or winding the strands around the common central longitudinal axis, one or more strands can be crossed over one another in the sense of a knitting process to produce a braid-like implant body.

Furthermore, the strands can be twisted or braided round a common core (mandrel), which is removed after the production process, for example by heat treating the implant body to vaporise or burn away the core.

However, the core can also be made from a heat-resistant material, which remains in the implant body even after it has been fabricated and given any subsequent treatment.

A further possibility is to carry out the twisting or braiding process around a central elongated element which performs the function of a winding mandrel during the production process. When the implant body has been made, the said central elongated element can be removed. However, it could also remain in the implant body and be made use of during the later intravascular positioning of the latter.

It is also conceivable for the implant body to be produced during its placing in the vessel. For this, the wires are introduced via a catheter designed so that during their deposition the wires are twisted and welded at their ends.

According to Claim 19 any known twisting, braiding or weaving method can be used to produce an implant body according to the invention.

Below, the invention is described in more detail with reference to the example embodiments illustrated in Figs. 1 to 7.

Fig. 1 shows a section at the end of an implant body 1, produced by twisting two platinum wires 2 and 3 about a central longitudinal axis 4. The twist direction is indicated by the arrow PF1. At the end 5 the wires 2 and 3 are welded together. At the points marked K the

wires 2 and 3 are in mutual contact. Along the wires 2, 3 of an implant body 1 placed in a vessel, there are flow channels S.

Fig. 2 shows an implant body 6 made of four wires 7, 8, 9 and 10 twisted together in the same twist direction PF2 around a central longitudinal axis 4'. As in the representation of Fig. 1, the individual wires 7, 8, 9 and 10 within the twisted implant body 6 each have the shape of spirals or coils offset relative to one another by a certain amount.

The implant body 11 shown in Fig. 3 has a braid-like structure. The implant body 11 is made from several wires 12 and 13 by a braiding process, which is carried out basically around the central longitudinal axis 4". During the braiding, successive pairs of wires 12, 13 are crossed over. In Fig. 3, for the sake of clarity this crossing over is shown as taking place around a temporary rotation axis 14. Basically, the crossing over can take place with a rotation direction PF4 which is in the same direction as PF3, but an opposite rotation direction PF5 is also possible.

This produces the braid 15. At the ends, the braided wires 12, 13 are joined together in pairs by welds 16.

Fig. 4 shows an implant body 17 made from filaments 18, 19, 20 and 21 by a twisting process about a central longitudinal axis 4'". The twist direction is indicated by the arrow PF6.

The twisting is carried out around a cylindrical ceramic core 22. After welding the filaments 18 to 21 at the end 23, the core 22 is removed. This produces a cylindrical implant body 17 with an interior channel 24.

Another production method can also be described with reference to Fig. 4. In this case the core is made of a synthetic filament. After completion of the twisting, the body so produced is cut along its length into short cylindrical sections, the filaments or wires being laser welded at their ends. During this, most of the core is vaporised or burned away. Residues of the core are then removed by an annealing treatment. The end product obtained is small, flexible cylindrical implant bodies.

In turn, Fig. 5 shows an end section of a braided implant body 25 produced by a braiding process around a mandrel 26. At the end 27 the wires 28, 29 are again welded together in pairs.

The mandrel 26 consists of a heat-resistant material and can remain in the implant body 25 even during a subsequent treatment. Of course, however, the mandrel 26 can consist of a combustible or vaporisable material. In the latter case a hollow space will be left behind in the implant body 25 after heat treatment.

Fig. 6a shows a pre-product 30' of an implant body 30, in which three metallic filaments 31, 32 and 33 are twisted around a mandrel 35 together with a plastic filament 34.

Fig. 6b shows the implant body 30 after the pre-product 30' has been heat treated. By heating, the plastic filament has been burned away or vaporised. This produces a helical channel 36 between the wires 31, 32, 33.

Fig. 7 shows a section of wire 37 whose thickness varies along its length. The wire 37 has length sections L_1 and L_2 with different cross-sections Q_1, Q_2.

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1	Implant body
2	Platinum wire
3	Platinum wire
4	Central longitudinal axis
4'	Central longitudinal axis
4"	Central longitudinal axis
4"'	Central longitudinal axis
5	End of 1
6	Implant body
7	Wire
8	Wire
9	Wire
10	Wire
11	Implant body
12	Wire
13	Wire
14	Temporary rotation axis
15	Mesh
16	Weld
17	Implant body
18	Wire
19	Wire
20	Wire
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22	Core
23	End of 17
24	Interior channel
25	Implant body
26	Mandrel
27	End of 25
28	Wire
29	Wire

30	Implant body 30' – Pre-product
31	Metal filament
32	Metal filament
33	Metal filament
34	Plastic filament
35	Mandrel
36	Channel
37	Wire
K	Contact point
L_1	Length section
L_2	Length section
PF1	Twist direction
PF2	Twist direction
PF3	Twist direction
PF4	Twist direction
PF5	Twist direction
PF6	Twist direction
Q_1	Cross-section
Q_2	Cross-section
S	Flow channel

Claims

1. Implant body for the selective endovascular influencing of the flow situation in a blood vessel, with a twisted strand of flexible material **characterised in that** at least two strands (2, 3, 7, 8, 9, 10, 12, 13, 18-21, 28, 29, 31-34, 37) are wound at least partially round a common central longitudinal axis (4, 4', 4", 4"') with a constant or alternating twist direction to produce an approximately centrally symmetric configuration.

2. Implant body according to Claim 1, **characterised in that** the strands (37) have length sections (L_1, L_2) of different cross-section (Q_1, Q_2).

3. Implant body according to Claims 1 or 2, **characterised in that** the strands (2, 3, 7, 8, 9, 10, 12, 13, 18-21, 28, 29, 31-34) are in contact with one another at least in sections.

4. Implant body according to any of Claims 1 to 3, **characterised in that** the strands (2, 3, 12, 13, 18-21, 28, 29) are connected together at least at one end (5, 16, 23, 27).

5. Implant body according to any of Claims 1, to 4, **characterised in that** at least two strands (18-21, 31-33) are twisted into essentially cylindrical spiral bodies with a common twist axis and the same twist direction.

6. Implant body according to any of Claims 1 to 4, **characterised in that** the strands are woven together in the manner of a braid.

7. Implant body according to any of Claims 1 to 6, **characterised in that** at least one helical channel (36) is formed through the strands (31-33).

8. Implant body according to any of Claims 1 to 7, **characterised in that** the strands (12, 13, 28, 29) form a cylindrical mesh (15).

9. Implant body according to Claim 8, **characterised in that** a longitudinal channel is provided in the mesh (15).

10. Implant body according to any of Claims 1 to 9, **characterised in that** the strands (18-21, 28, 29, 31-34) are wound around a core (22, 26, 35).

11. Implant body according to Claim 10, **characterised in that** the core projects beyond the strands at least at one end, and is connected to the strands by a joint.

12. Implant body according to any of Claims 1 to 11, with an active substance that influences the nature of the body tissue and/or of a body fluid.

13. Implant body according to any of Claims 1 to 12, with a radioactive substance that influences the nature of the body tissue and/or of a body fluid.

14. Implant body according to any of Claims 1 to 13, **characterised in that** at least one strand (34) consists of a material that can be eliminated by the effect of heat.

15. Method for producing an implant body, **characterised in that** at least two strands (2, 3, 7, 8, 9, 12, 13, 18-21, 28, 29, 31-34, 37) of a flexible material are twisted at least partially around a common central longitudinal axis (4, 4', 4", 4"') with a constant or alternating twist direction to form an approximately centrally symmetric configuration.

16. Method according to Claim 15, **characterised in that** the strands (12, 13, 18-21) are twisted around the central longitudinal axis (4", 4"') in such manner that a central hollow space is formed around the central longitudinal axis (4", 4"').

17. Method according to Claims 15 or 16, **characterised in that** the strands (12, 13, 28, 29) are crossed over to form a cylinder.

18. Method according to any of Claims 15 to 17, **characterised in that** the strands (18-21, 28, 29, 31-34) are wound around a core (22, 26, 33).

19. Use of a twisting, braiding or weaving process known in its own right to produce an implant body according to any of Claims 1 to 15.

With 3 page(s) of drawings
